

52, 53
53. (New) The nucleic acid molecule of claim 52, wherein said nucleic acid molecule is at least 95% identical to SEQ ID NO:3.

54. (New) The nucleic acid molecule of claim 53, wherein said nucleic acid molecule is at least 98% identical to SEQ ID NO:3.

55. (New) The nucleic acid molecule of claim 54, wherein said nucleic acid molecule is at least 99% identical to SEQ ID NO:3.

56. (New) A nucleic acid molecule comprising at least 30 contiguous nucleotides of the nucleic acid molecule of SEQ ID NO:3.

57. (New) The nucleic acid molecule of claim 56, wherein said nucleic acid molecule comprises at least 60 contiguous nucleotides of the nucleic acid molecule of SEQ ID NO:3.--

IN THE ABSTRACT:

Please insert the enclosed page entitled "ABSTRACT" after the claims.

REMARKS

Reconsideration of this application is respectfully requested. Claim 1-41 have been canceled. Claims 42-57 are new and are fully supported throughout the specification. No new matter enters by amendment.

Applicant acknowledges receipt of the initialed copy of Form 1449 filed February 5, 2001. However, applicant submitted another Information Disclosure Statement with Form 1449 on October 16, 2000 (copy enclosed), of which applicant has not received an initialed copy. Applicant requests that an initialed copy of this Form 1449 be returned to applicant.

The Examiner alleges that the specification does not contain an Abstract. An Abstract is enclosed.

Rejections under 35 U.S.C. § 101

Claims 13-15, 22-24, and 35 were rejected under 35 U.S.C. § 101 for allegedly having no apparent or disclosed utility. Applicant traverses the rejection.

To violate 35 U.S.C. § 101, the claimed product must be totally incapable of achieving a useful result. M.P.E.P. § 2107.01 at p. 2100-33, col. 1-2; *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 24 U.S.P.Q.2d 1401,1412 (Fed. Cir. 1992). When a properly claimed invention meets at least one stated objective, utility under 35 U.S.C. § 101 is clearly shown. *Raytheon Co. v. Roper Corp.*, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983).

Applicant's claimed invention fulfills the requirements of 35 U.S.C. § 101. Applicant asserted that IL-1 delta is useful for probes to identify nucleic acid encoding proteins having IL-1 delta activity. (Specification at 36, lines 4-5.) Due to the RNA expression pattern of IL-1 delta, probes based on the DNA sequence of SEQ ID NO:3 can be used to detect lymph node, thymus, tonsil, brain placenta, lung, skeletal muscle, prostate, and testis tissue and cell types by methods such as *in situ* hybridization. (*Id.* at 36, lines 28-30). In addition, all or a portion of the nucleic acids of SEQ ID NO:3, including oligonucleotides, can be used by those skilled in the art using well-known techniques to identify human chromosome 2, to analyze abnormalities associated with gene mapping to chromosome 2, to distinguish conditions in which this marker is rearranged or deleted, and as a positional marker to map other genes of unknown location. (*Id.* at 37, lines 1-32.)

The asserted utilities are specific. A specific utility is one "that is **specific** to the subject matter claimed" in contrast to "a **general** utility that would be applicable to the broad class of the invention." M.P.E.P. § 2107.01 at p. 2100-32, col. 1. All polynucleotides would not be useful for the asserted utilities. For example, all polynucleotides could not detect the 2q11-12 region of chromosome 2 or the specific RNA detected by applicant. Similarly, all polynucleotides could not detect RNA expression in lymph node, thymus, tonsil, brain placenta, lung, skeletal muscle, prostate, and testis tissue and cell types by methods such as *in situ* hybridization. Therefore, these utilities are specific.

The asserted utilities are also substantial since they are well-recognized to be central to the fields of cell biology and chromosome mapping. For example, IL-1 delta could be used to discriminate alterations of the 2q11-12 region of chromosome 2 from other chromosomal alterations. In addition, IL-1 delta could be used to detect specific tissue and cell types by methods such as *in situ* hybridization. A substantial utility is one "that defines a 'real world' use." M.P.E.P. § 2107.01 at 2100-32, col. 1. A utility that requires further research is not a substantial utility. *Id.* The use of IL-1 delta nucleic acid molecules to discriminate alterations of the 2q11-12 region of chromosome 2 from other chromosomal alterations and to detect specific tissue and cell types are real world uses. No further research is required for these utilities. Therefore, applicant's utilities are substantial.

Applicant's utilities are "real world" uses. Consequently, in contrast to the Examiner's allegations, the current situation is not analogous to that faced in *Brenner v. Manson*, 383 U.S. 519, 148 U.S.P.Q. 689 (1966), where the Court found a lack of utility.

Rather, since applicant's utilities have specific benefit in currently available form, *Brenner v. Manson* supports a finding of utility for applicant's claimed invention. See *id.*

Therefore, applicant has asserted a variety of utilities for the claimed invention. Undoubtedly, applicant's invention is not totally incapable of achieving a useful result. Consequently, applicant's claimed invention cannot be rejected for lacking utility. M.P.E.P. § 2107.01 at p. 2100-33, col. 1-2; *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 24 U.S.P.Q.2d at 1412. Accordingly, applicant respectfully requests withdrawal of the rejection.

Moreover, when the disclosure asserts a utility, the Office has the initial burden of challenging a presumptively correct assertion of utility in the disclosure. M.P.E.P. § 2107.02 at p. 2100-40, col. 2; *In re Brana*, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). To meet this initial burden, the Office must "make a *prima facie* showing that the claimed invention lacks utility" and the Office "must provide a sufficient evidentiary basis for factual assumptions relied upon in establishing the *prima facie* case." M.P.E.P. § 2107.02 at p. 2100-40, col. 2. Indeed, the M.P.E.P. states:

Any rejection based on lack of utility should include a **detailed explanation** why the claimed invention has no specific and substantial credible utility. Whenever possible, the Examiner should provide **documentary evidence** If documentary evidence is not available, the Examiner should **specifically explain** the factual basis for his or her factual conclusions.

M.P.E.P. § 2107.02 at p. 2100-41, col. 1, emphasis added).

Only after the Office provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's

asserted utility. M.P.E.P. § 2107.02 at 2100-42, col. 1; *In re Brana*, 34 U.S.P.Q.2d at 1441. The initial burden is on the Office.

The Office has not met this burden. The Office has provided **no explanation** as to why the Office believes that one of ordinary skill in the art would reasonably doubt applicant's asserted utilities. Accordingly, applicant respectfully requests withdrawal of the rejection.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 13-15, 22-24, and 35 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly not having either a specific and substantial asserted utility or a well established utility for the same reasons set forth for the rejections under 35 U.S.C. § 101.

Applicant traverses the rejection. For the reasons detailed above, the skilled artisan would understand how to use the claimed invention. Accordingly, applicant respectfully requests withdrawal of the rejection.

Claims 13-15, 22-24, and 35 were rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not reasonably provide enablement for a nucleic acid molecule that encodes a fragment of the polypeptide of SEQ ID NO:4, wherein the fragment binds to an IL-1 delta counterstructure, and a nucleic acid molecule that hybridizes to either strand of a denatured, double-stranded DNA comprising the nucleic acid encoding SEQ ID NO:4. The Examiner further alleges that predictability in the art requires identification of the fragment length, starting, and ending nucleic acids that bind to the counterstructure molecules. With respect to claim 13(b)-(c) and claim 22, the Examiner alleges that one skilled in the art would not know what

are the counterstructure molecules and what is included or what is excluded from the list of such counterstructure molecules. With respect to claim 13(c), the Examiner alleges that no guidance is provided as to how one skilled in the art should be selecting the polypeptide variants.

Applicant traverses the rejection. One of skill in the art would know from the specification that the types of counterstructure molecules encompassed by the term "counterstructure" are those expressed by cells. (Specification at 40-41.) To more particularly point out and distinctly claim the subject matter that applicant regards as the invention, new claims 42 and 46 recite "wherein the fragment binds to cells expressing an IL-1 delta receptor." Accordingly, applicant respectfully submits that the rejection has been obviated by amendment and requests withdrawal of the rejection.

Furthermore, fragments of IL-1 delta can be made by many techniques well-known in the art, for example, as discussed on pages 14-16 of the specification. Examples of IL-1 delta polypeptide fragments include polypeptides truncated for one to five amino acids from the N- or C- termini. (Specification at 16, lines 15-19.) Assays for determining binding of IL-1 delta polypeptide fragments to IL-1 delta counterstructures are described on pages 34 and 35 of the specification. Consequently, the generation of IL-1 delta fragments is predictable and does not require undue experimentation. Accordingly, applicant respectfully requests withdrawal of the rejection.

Furthermore, applicant provides detailed guidance as to how one skilled in the art should be selecting the polypeptide variants on pages 17-24 of the specification. For example, a given amino acid may be replaced by a residue having similar physiochemical characteristics. (Specification at 18, lines 12-18.) Also, N-glycosylation

sites can be modified to preclude glycosylation. (*Id.* at 19, lines 2-12.) Sequences encoding Cys residues can be altered to cause the Cys residues to be deleted or replaced with other amino acids. (*Id.* at 19, lines 13-16.) KEX2 protease processing sites can be inactivated. (*Id.* at 19, lines 20-24.) Accordingly, applicant respectfully requests withdrawal of the rejection.

In addition, applicant has added new claims 52-59. New claims 52-59 are not limited to nucleic acids that encode a polypeptide that binds to an IL-1 delta counterstructure. Rather, claims 52-59 encompass nucleic acids without regard to the ability of any encoded polypeptide to bind to an IL-1 delta counterstructure. Pages 36-39 of the specification detail many specific and substantial uses for the claimed nucleic acid molecules as probes and primers for IL-1 delta nucleic acids. The identity of the encoded polypeptide is not a limitation of these claims. Accordingly, new claims 52-59 obviate the rejection.

Claims 22-24 were rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does reasonably provide enablement for the claimed invention. The Examiner contends that the specification does not describe which polypeptide species retain the activity of IL-1 delta. The Examiner alleges that a single amino acid change can have a dramatic effect on a protein's function. The Examiner concludes that undue experimentation would be required to practice the claimed invention.

Applicant traverses the rejection. As discussed above, variants and fragments of IL-1 delta can be made by many techniques well-known in the art, for example, as discussed on pages 14-16 of the specification. Nucleic acids that hybridize to IL-1 delta nucleic acids can be determined using hybridization assays as described on page 12 of

the specification. Assays for determining binding of IL-1 delta polypeptide fragments to IL-1 delta counterstructures are described on pages 34 and 35 of the specification. With applicant's specification, only routine screening would be required. Consequently, the generation of IL-1 delta fragments is predictable and does not require undue experimentation. Accordingly, applicant respectfully requests withdrawal of the rejection.

Claims 22-24 were rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly does not provide an adequate written description for the claimed invention. The Examiner contends that conception of the claimed invention cannot be achieved until reduction to practice has occurred, and that reduction to practice has not occurred. Therefore, the Examiner concludes that applicant has not provided sufficient evidence to show possession of the claimed invention at the time of filing.

Applicant traverses the rejection. Apparently, the Examiner requires applicant to have a working example. However, the mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it. *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 U.S.P.Q. 2d 1302, 1304 (Fed. Cir. 1987). A lack of a working example appears to be the only basis for the Examiner's rejection. Such a basis is insufficient. See *id.* Accordingly, applicant respectfully requests withdrawal of the rejection.

Furthermore, as discussed above, new claims 52-59 are not limited to nucleic acids that encode a polypeptide that binds to an IL-1 delta counterstructure. Accordingly, new claims 52-59 obviate the rejection.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 13 and 22 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in the recitation "the fragment binds to an IL-1 counterstructure." The Examiner contends that it is not clear what is meant by "counterstructure."

Applicant traverses the rejection. One of skill in the art would know from the specification that the types of counterstructure molecules encompassed by the term "counterstructure" are those expressed by cells. (Specification at 40-41.) In addition, new claims 42 and 46 recite "wherein the fragment binds to cells expressing an IL-1 delta receptor." Accordingly, applicant respectfully submits that the rejection has been obviated by amendment and requests withdrawal of the rejection.

Applicant submits that this application is now in condition for allowance. If the Examiner should disagree, the Examiner is invited to contact the undersigned to discuss any remaining issues.

If there is any fee due in connection with the filing of this paper, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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